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Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 2945025

April 23, 2002

Anthony S. Friscia, President
A. Friscia Seafoods, Inc.
555 Francisco Street
San Francisco, California 94133

WARNING LETTER

Dear Mr. Friscia:

On November 19-20 and December 3, 2001, we inspected your seafood processing facility, located at 555 Francisco Street, San Francisco, CA. We found that you have serious deviations from the seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause your Ahi, Mahi, Tombo Tuna, and Cooked Crab to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fishery products have been prepared, packed, and held under insanitary conditions whereby they may be rendered injurious to health. You may find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov. See attached handout, which gives information on how to obtain the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001.

Your serious HACCP deviations are as follows:

1. You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plans for Ahi, Mahi, and Tombo Tuna list critical limits, "Cooler temp not to exceed [redacted]°F for more than 4 hours in a 24 hour period. Cooler temp not to exceed [redacted]°F control cumulative," at the receiving critical control point that is not adequate to control histamine formation.

   FDA recommends that either:

   All lots received are accompanied by transportation records (e.g., temperature recording chart) that show the fish were held at or below 40°F throughout transit

   OR

For fish held under ice or other cooling media at the time of delivery--there is an adequate quantity of ice or other cooling media to completely surround the product .

OR

For fish delivered with a total transit time of 4 hours or less, the internal temperature of a representative number of fish in the lot at the time of delivery is not more than 40°F.

2. You must have a HACCP plan that lists the critical control points to comply with 21 CFR 123.6(c)(2). However,

   a. Your firm's HACCP plans for Ahi, Mahi, and Tombo Tuna do not list the critical control point of storage for controlling the food safety hazard of scombrotoxin formation. FDA recommends that refrigerated seafood products be held at 40°F or less and that the temperature be monitored continuously by means of a temperature data recorder or by using an alarm system.

   b. Your firm's HACCP plan for Cooked Crab does not list the critical control point of storage for controlling the food safety hazard of bacterial pathogen growth. FDA recommends that refrigerated seafood products be held at 40°F or less and that the temperature be monitored continuously by means of a temperature data recorder or by using an alarm system.

3. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate to comply with 21 CFR 123.7(b). However, your corrective action plan for Cooked Crab at the cooking critical control point is not appropriate. Your corrective action plan does not address the corrective action to be taken when your time-temperature critical limit is not met (i.e., [redacted] minutes at [redacted] °F). Your corrective action plan should also address correcting the cause of the deviation and ensuring that unsafe product (i.e., under-processed product) does not reach consumers.

4. You must maintain sanitation control records that document the monitoring and corrections applied to the following to comply with 21 CFR 123.11(c):
   - Safety of water
   - Condition and cleanliness of food-contact surfaces
   - Prevention of cross-contamination
   - Maintenance of hand-washing, hand-sanitizing, and toilet facilities
   - Protection from adulterants
   - Labeling, storage, and use of toxic compounds
   - Employee health conditions
   - Exclusion of pests

5. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plan for Cooked Crab does not list the food safety hazard of natural toxins.

6. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the following areas of sanitation with sufficient frequency to ensure control:

   a. Your firm failed to monitor the condition and cleanliness of food contact surfaces as evidenced by our investigator observing an employee using a telephone while wearing latex gloves and subsequently handling ready-to-eat crabmeat without washing and sanitizing the gloves.

   b. Your firm failed to prevent cross-contamination from insanitary object to food or food-packaging material as evidenced by our investigator observing employees routinely packing ready-to-eat crabs into recycled boxes that were previously used to package fresh and frozen crabs.

At the conclusion of the inspection, the deviations were listed on Form FDA 483 and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR 110).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. More than four months have elapsed since FDA inspection. Please provide this office with information on what progress you have made in achieving FDA compliance with the seafood HACCP regulations. You may wish to include in your response documentation that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District